

lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, [comprising, together with pharmaceutical excipients suitable for topical application,] each such dosage amount comprising a therapeutically effective non-toxic (to the patient) dosage amount of a drug which inhibits prostaglandin synthesis [administered with, or carried in,] and an effective non-toxic dosage amount of hyaluronic acid and/or salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid [(preferably hyaluronic acid and salts thereof) sufficient] to [facilitate the drug's penetration through the skin and tissue (including any scar tissue) at] transport (to facilitate or cause the transport of the drug to the site of the pathology and/or trauma of the disease or condition requiring treatment, to block prostaglandin synthesis.

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2. (Amended) The [combination or formulation] composition of Claim 1 wherein the drug is a non-steroidal anti-inflammatory drug (NSAID).

3. (Amended) The [combination or formulation] composition of Claim 2 wherein the hyaluronic acid and/or salts thereof [(for example, the sodium salt)] and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid is hyaluronic acid or a salt thereof.

4. (Amended) The [formulation or combination] composition of Claim 3 wherein the NSAID is selected from diclofenac, indomethacin,

naproxen, and (+,-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

5. (Amended) The [formulation or combination] composition of Claim 3 wherein [the NSAID is] selected from IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetylsalicylic acid and Flunixin] the amount of the hyaluronic acid or salt thereof is in excess of 5-6 mg per dosage and has a molecular weight less than about 750,000 daltons.

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6.(Amended) A method of treating a disease or condition of the skin and exposed tissue [for example] comprising, basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which comprises administering topically to the mammal a [combination] non-toxic dosage amount of a composition comprising, [together with] in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective (to treat and resolve the disease, condition or lesion), non-toxic (to the patient) dosage amount of a drug which inhibits prostaglandin synthesis [administered with, or carried in,] and an amount of hyaluronic acid and/or salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid sufficient to transport [facilitate the transport of] the [drug's penetration through] drug into the skin and/or exposed tissue (including

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any scar tissue) at the site of the disease or condition to be treated to block prostaglandin synthesis.

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8. (Amended) The method of Claim 6 wherein the hyaluronic acid and salts thereof [(for example, the sodium salt)] and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid is hyaluronic acid or a salt thereof.

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10. (Amended) The method of Claim 9 wherein the NSAID is selected from diclofenac, indomethacin, naproxen, and (+,-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

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11. (Amended) The method of Claim 9 wherein [the NSAID is selected from IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetylsalicylic acid and Flunixin] the amount of the hyaluronic acid or salt thereof is in excess of 5-6 mg per dosage and has a molecular weight less than about 750,000 daltons.

12. (Amended) The method of Claim 7 wherein the hyaluronic acid and salts thereof [(for example, the sodium salt)] and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid is hyaluronic acid or a salt thereof.

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14. (Amended) The method of Claim 13 wherein the NSAID is selected from diclofenac, indomethacin, naproxen, and (+,-) tromethamine salt of ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

15. (Amended) The method of Claim 13 wherein [the NSAID is selected from IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetyltsalicylic acid and Flunixin] the amount of the hyaluronic acid or salt thereof is in excess of 5-6 mg per dosage and has a molecular weight less than about 750,000 daltons.

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16. Transdermal delivery of a therapeutically effective amount of a drug which prohibits prostaglandin synthesis applied topically to treat a disease or condition of the skin and exposed tissue [for example,] comprising basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal, the delivery comprising administering in a pharmaceutically acceptable form, topically a therapeutically effective (to treat the disease or condition of the skin or exposed tissue) non-toxic (to the patient) dosage amount of such drug [with a sufficient] and an effective dosage amount of hyaluronic acid and/or salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and sub-units of hyaluronic acid sufficient to transport, [or] (facilitate the transport of], the drug to the site of the disease or condition to block prostaglandin synthesis.

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19. (Amended) The delivery of Claim 18 wherein the NSAID is selected from diclofenac, indomethacin, naproxen, and (+,-) tromethamine salt of

~~ketorolac, IBUPROFEN, PIROXICAM, Propionic Acid derivatives,
aceetyl salicylic acid and Flunixin.~~

20. (Amended) The delivery of Claim 18 wherein [the NSAID is selected from IBUPROFEN, PIROXICAM, Propionic Acid derivatives, aceetyl salicylic acid and Flunixin] the amount of the hyaluronic acid or salt thereof is in excess of 5-6 mg per dosage and has a molecular weight less than about 750,000 daltons.

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cont.

21.(Amended) [Use of a combination or formulation] The composition of Claim 3 to treat a disease or condition of the skin and exposed tissue [for example,] comprising basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, [the combination and formulation comprising together with pharmaceutical excipients suitable for topical application, a therapeutically effective (to treat and resolve the condition or disease of the skin or exposed tissue), non-toxic (to the patient) amount of a drug which inhibits prostaglandin synthesis administered with, or carried in, an amount of hyaluronic acid and/or salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and/or sub-units of hyaluronic acid sufficient to facilitate the drug's penetration through the skin and tissue (including any scar tissue) at the site to be treated to block prostaglandin

synthesis] wherein the amount of hyaluronic acid or salt thereof is about 20 mg/cm².

22. (Amended) The [use] composition of Claim 21 wherein the [hyaluronic acid and/or salts thereof and/or homologues, analogues, derivatives, complexes, esters, fragments, and sub-units of hyaluronic acid, preferably hyaluronic acid and salts thereof is selected from] hyaluronic acid and/or salts thereof has a molecular weight less than about 750,000 daltons.

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concl.* 23. (Amended) The [use] composition of Claim [21] 22 wherein the drug is a non-steroidal anti-inflammatory agent (NSAID).

24. (Amended) The [use] composition of Claim 23 wherein the NSAID is selected from diclofenac, indomethacin, naproxen, and (+,-) tromethamine salt of ketorolac.

25. (Amended) The [use] composition of Claim 23 wherein the NSAID is selected from IBUPROFEN, PIROXICAM, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

REMARKS

Claims 1 to 25 as amended remain in the application. The claims have been amended to more particularly describe the invention. No new subject matter has been added to claims. The amendments are based on the disclosure. For example, the specific amounts of hyaluronic acid and salts thereof specified in Claims 5, 11, 15, 20 and 21 are taught for example at page 31, line 3, page 50, lines 6 to 8 and page 50, lines 18